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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,157	06/16/2006	Viktor Menart	33581-US-PCT	5099

7590 06/08/2010

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
06/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,157	MENART ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission and amended claims filed on 2/24/2010 were entered and responded to in the Advisory Action mailed 3/3/2010. Applicant did not file any new submissions or arguments with the Request for Continued Examination on 4/19/2010. Accordingly, the rejections of record are maintained and the instant Office Action is FINAL.

Formal Matters

2. Claims 5 and 13-16 have been cancelled by Applicant. Claims 1-4 and 6-12 are pending and under examination as they are drawn to the species of G-CSF.

Response to Arguments

Objections/Rejections Maintained

Claim Objections

3. Claim 12 remain objected to because of the following informalities: The examiner noted in the Advisory Action that the status identifier for claim 12 is improper. No amendment was made to claim 12. Claim 12 should be indicated as previously presented, since it appears to be the same claim previously presented. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 10, and 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by Miyazawa et al (US Patent 5,500,416, 19 March 1996) (cited in Applicant's IDS of 6/16/2006), for the reasons of record and the reasons set forth herein.

Applicant's submission and amended claims filed on 2/24/2010 were entered and responded to in the Advisory Action mailed 3/3/2010. Applicant did not file any new submissions or arguments with the Request for Continued Examination on 4/19/2010.

Applicant argued that Miyazawa does not teach the use of NDSBs as part of a composition containing an active pharmaceutical agent (Remarks, p. 4). Applicant distinguishes NDSB from other surfactant or detergent sulfobetaines (Remarks, pp. 5 and 6).

Applicant's arguments have been fully considered, but they are not persuasive. Applicant defines an NDSB at p. 3 of the specification as a sulphobetaine that does not form micelles in water solution. The compositions of the cited art meet this limitation along with the structural limitations of the NDSBs recited in claim 1, as amended. As stated of record, Miyazawa et al., do, in fact, teach compositions comprising active pharmaceutical ingredients, including pharmaceutically acceptable excipients, and non-detergent sulfobetaine (NDSB) (column 2, lines 61 to column 3, line 32; column 5, line 47 to column 7, line 58) (see also claims 1, 6, 7, and 8) (compare instant claims 1, 2, 10, and 12). Examples of various NDSBs are taught at column 3, lines 22-32; column 4, lines 32-46; and claims 7 and 9.

6. Claims 1-4, 6, and 8-12 remain rejected under 35 U.S.C. 102(e) as being anticipated by Menart et al., WO 2004/015124 (published 19 February 2004, priority to 11 June 2003; published in English and designating the US), for the reasons of record and the reasons set forth herein.

Applicant's submission and amended claims filed on 2/24/2010 were entered and responded to in the Advisory Action mailed 3/3/2010. Applicant did not file any new submissions or arguments with the Request for Continued Examination on 4/19/2010.

Applicant argues that the Menart '124 publication does not teach the compositions suitable for parenteral administration, as required by the amended claims. Applicant's argument has been fully considered, but it is not persuasive. The amended claims read on a composition of matter that is suited for pharmaceutical administration. The Menart '124 publication teaches compositions and methods of producing G-CSF using non-classical inclusion bodies and solubulizing those inclusion bodies in a gentler, less-toxic manner than ordinarily used in the art (see pages 2-3). Menart states that "[i]n most cases solubilization of classical inclusion bodies requires the use of strong detergents which are toxic and are non-nature friendly and are serious environmental pollutants. Their use is also uneconomical because

safe removal after the end of the process is an additional cost and is time consuming" (pp. 2 to 3). By using NDSB in making a G-CSF pharmaceutical composition, Menart teaches that you do not have to remove any remaining NDSB at the end of the process, resulting in a more economical, safe, environmentally friends, less-toxic, and time-saving end-product. Menart teaches pharmaceutical compositions in claim 37 and Example 12 (p. 34). Accordingly, the compositions taught by Menart would have NDSBs in the final pharmaceutical composition because the compositions were not subject to post-manufacture removal of the NDSBs.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 7 remains rejected in addition to claims 1-6 and 8-12 under 35 U.S.C. 103(a) as being unpatentable over Menart et al., WO 2004/015124 (published 19 February 2004, priority to 11 June 2003;

published in English and designating the US) and Vuillard et al., (Biochem J. 1995;305:337-343), for the reasons of record and the reasons set forth herein.

Applicant's submission and amended claims filed on 2/24/2010 were entered and responded to in the Advisory Action mailed 3/3/2010. Applicant did not file any new submissions or arguments with the Request for Continued Examination on 4/19/2010.

Applicant argues that the Menart '124 publication does not teach the compositions suitable for parenteral administration, as required by the amended claims. Applicant's argument has been fully considered, but it is not persuasive. The amended claims read on a composition of matter that is suited for pharmaceutical administration. The Menart '124 publication teaches compositions and methods of producing G-CSF using non-classical inclusion bodies and solubulizing those inclusion bodies in a gentler, less-toxic manner than ordinarily used in the art (see pages 2-3). Menart states that "[i]n most cases solubilization of classical inclusion bodies requires the use of strong detergents which are toxic and are non-nature friendly and are serious environmental pollutants. Their use is also uneconomical because safe removal after the end of the process is an additional cost and is time consuming" (pp. 2 to 3). By using NDSB in making a G-CSF pharmaceutical composition, Menart teaches that you do not have to remove any remaining NDSB at the end of the process, resulting in a more economical, safe, environmentally friends, less-toxic, and time-saving end-product. Menart teaches pharmaceutical compositions in claim 37 and Example 12 (p. 34). Accordingly, the compositions taught by Menart would have NDSBs in the final pharmaceutical composition because the compositions were not subject to post-manufacture removal of the NDSBs. Vuilliard need not teach what is taught by Menart.

Conclusion

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647